



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

April 16, 2015

Ceremed Incorporated  
Ms. Chelsea Mitchell  
Vice President of Regulatory Affairs  
3643 Lenawee Avenue  
Los Angeles, California 90016

Re: K141880

Trade/Device Name: Biopor<sup>®</sup> Porous Polyethylene Implants  
Regulation Number: 21 CFR 878.3500  
Regulation Name: Polytetrafluoroethylene with carbon fibers composite implant material  
Regulatory Class: Class II  
Product Code: KKY  
Dated: February 24, 2015  
Received: March 6, 2015

Dear Ms. Mitchell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**David Krause -S**

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## **V. INDICATIONS FOR USE:**

510 (k) Number (if known): K141880

**Device Name:** Biopor<sup>®</sup> Porous Polyethylene Implants

### Indications For Use:

Biopor® Porous Polyethylene Implants in block, sheet, and anatomical shapes are intended for the augmentation or reconstruction of the maxillofacial skeleton.

Prescription Use   X    
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

## Division Sign-Off

510(k) Number \_\_\_\_\_

**IV. GENERAL INFORMATION:**

**A. DEVICE NAME:**

- a. Common/Usual Name:** Porous High Density Polyethylene (HDPE) Surgical Implant
- b. Proprietary Name:** Biopor<sup>®</sup>, AOC<sup>™</sup> Porous Polyethylene, Cerepor<sup>™</sup>,  
In the future other brand names may be used by individual licensees.
- c. Classification Name:** Polytetrafluoroethylene with carbon fibers composite implant material (per 21 CFR section 878.3500)

**B. DEVICE SPONSOR:**

- a. Manufacturer:** Ceremed, Inc.  
3643 Lenawee Ave.  
Los Angeles, California 90016  
Tel: (310) 815-2125  
Fax: (310) 815-2130
- b. Establishment Registration No:** 3004961344  
Owner/Operator # 9063721
- c. Sterilization Sites:**  
  
Sterigenics  
IBA Advanced Materials Division  
San Diego, California 92121  
Phone (858) 271-6330  
Fax (858) 271-0957

**C. CLASSIFICATION:**

- a. Class:** II
- b. Product Code:** KKY
- c. Panel:** Surgical, Orthopedic, and Restorative Devices

**D. PERFORMANCE STANDARDS:** None established

**E. SHELF LIFE:** 5 years